K003313

JAN 11 2001

ATTACHMENT #7

510K SUMMARY

Contact Person:
Ms. Kelly J. Rowland
Sr. Specialist, Regulatory Affairs
The Kendall Company
444 McDonnell Blvd.
Hazelwood, MO63042
Phone: (314) 895-4100 x407
Date Prepared: October 18, 2000

Device:

Brand Name:	Filac™ FasTemp™ Electronic Thermometer
FDA Classification Name:	Clinical Electronic Thermometer, per 21 CFR 880.2910
Common or Usual Name:	Electronic Thermometer

Predicate Devices: Filac™ FasTemp™ Electronic Thermometer is substantially equivalent in intended use, function and composition to Welch Allyn™ SureTemp® Electronic Thermometer (510(k) K96464).

Device Description/Intended Use: The Filac™ FasTemp™ Electronic Thermometer and probes are non-sterile reusable devices. The probe covers are clean, ready to use, "single use" covers. The thermometer is used to measure a patient's temperature by oral, axillary, or rectal method. The Filac™ FasTemp™ Electronic Thermometer also may be used to measure patient's pulse rate.

The Filac™ FasTemp™ Electronic Thermometer is a lightweight, hand held unit with a mountable storage base. The unit comes equipped with a standard but interchangeable "BLUE" probe and isolation chamber for oral and axillary temperature measuring. The "RED" probe and isolation chamber (sold separately) is used strictly for rectal temperature measuring. By having the color-tinted probes and isolation chambers, this limits the chance of patient cross contamination. It also has a last temperature "RECALL" feature for user convenience. The Filac™ FasTemp™ Electronic Thermometer may also be used to measure a patient's pulse rate.

The Filac™ FasTemp™ Electronic Thermometer is equipped with an electronic system in the mountable storage base in order to deter unit theft. The thermometer will be disabled after a preset number of temperatures have been taken. To reactivate the thermometer it must be returned momentarily to any Filac™ FasTemp™ storage base when indicated by a display icon on the unit.

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510K SUMMARY (Continued)

Summary of Technological Characteristics: The Filac™ FasTemp™ Electronic Thermometer's main design change being incorporated compared to other currently marketed Filac™ Electronic Thermometers is a faster average predict time in temperature measuring and an anti-theft electronic mechanism. Also, the unit is more ergonomically shaped and lighter in weight. All other aspects are identical to current Filac™ Electronic Thermometers. The Filac™ FasTemp™ Electronic Thermometer will conform to *Standard Specification for Electronic Thermometers for Intermittent Determination of Patient Temperature, ASTM E 1112, 1991.*

The new Filac™ FasTemp™ Electronic Thermometer is substantial equivalent in materials, design and intended use to the SureTemp® Electronic Thermometers marketed by Welch Allyn™.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 11 2001

Ms. Kelly J. Rowland
Senior Specialist of Regulatory Affairs
The Kendall Company
444 McDonnell Boulevard
Hazelwood, Missouri 63042

Re: K003313
Trade Name: Filac™ FastTemp™ Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: January 2, 2000
Received: January 8, 2000

Dear Ms. Rowland:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ATTACHMENT #8

INDICATIONS FOR USE STATEMENT

510(k) Number: Pending Assignment from FDA

Device Name: Filac™ FastTemp Electronic Thermometer

Indications for Use: The Filac™ FasTemp™ Electronic Thermometer is used to measure a patient's temperature by oral, axillary, or rectal method in less than 8 seconds (1 minute for adult axillary). The Filac™ FasTemp™ Electronic Thermometer timer aids in measuring a patient's pulse rate.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-the-Counter Use _____
(*Per 21 CFR 801.109*)

Patricia Cucenite

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K003343